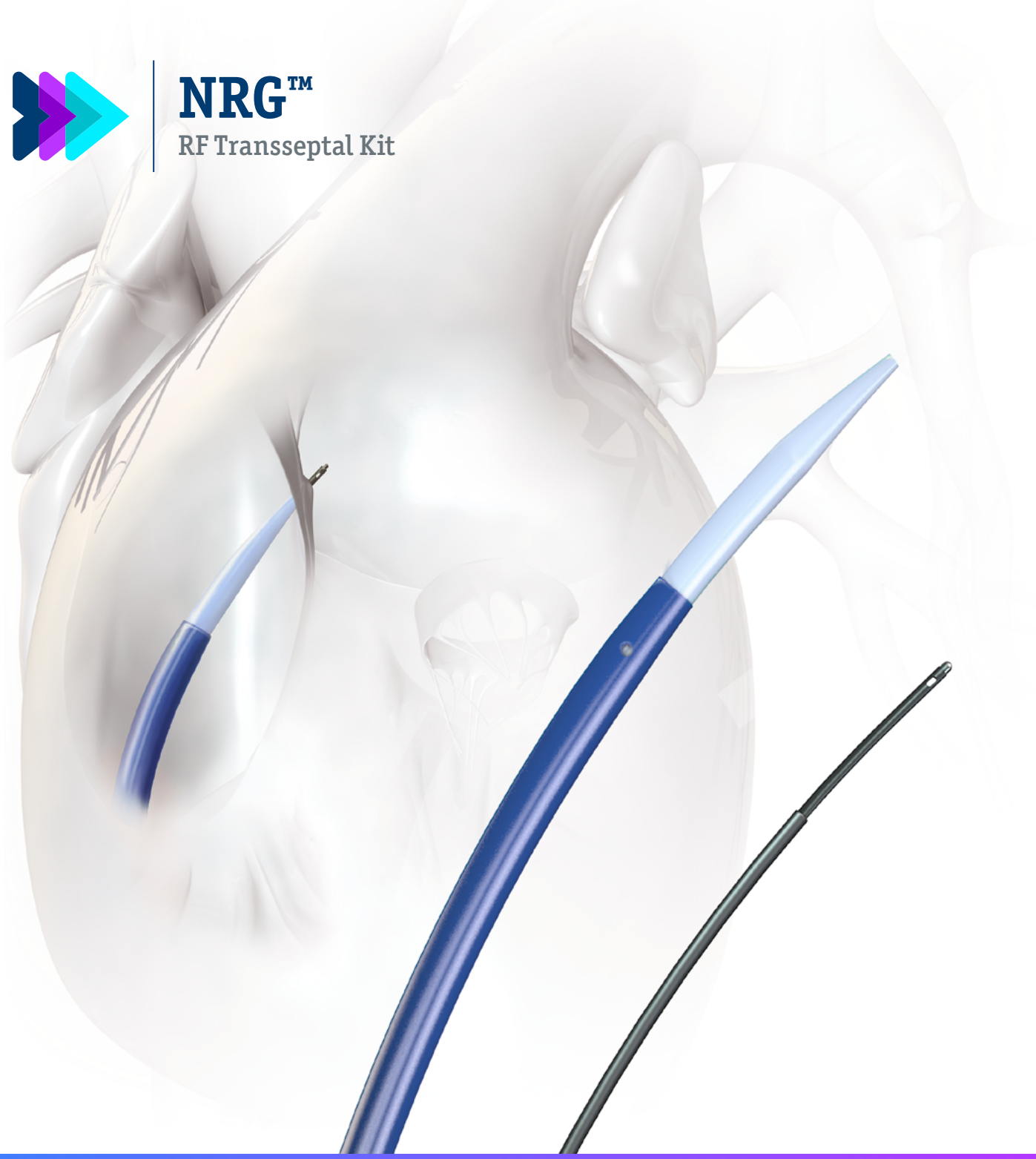
Boston Scientific
Advancing science for life™

NRG™

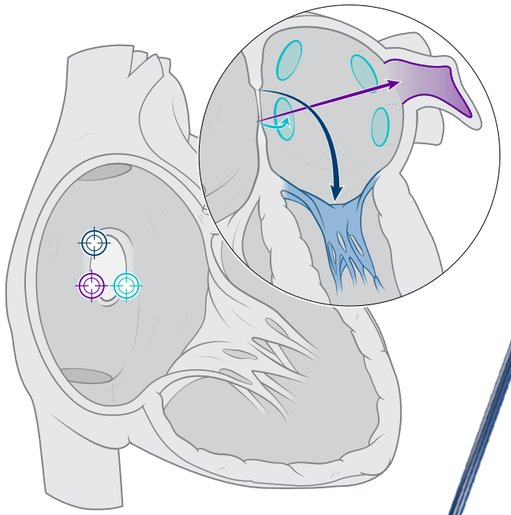
RF Transseptal Kit



TAKE CONTROL OF YOUR CROSSING™

TARGET

Optimize transseptal location to save time; deliver therapy on target.[1,2]



Pulmonary Vein Isolation
Mitral Valve Repair
Left Atrial Appendage Closure

NRG™ Transseptal Needle

Blunt Tip

Fine tune your position on the septum before crossing

Radiopaque Tip

Control your positioning by visualizing needle tip location

TorFlex™ Transseptal Guiding Sheath

Controlled Torque

Special braid composite design for ideal torque transmission

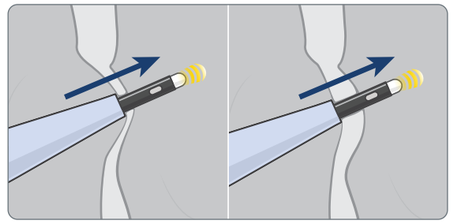
BE PRECISE. SAVE TIME.™

CROSS

NRG™ Transseptal Needle

Proven RF Puncture Technology

Reliably cross normal, aneurysmal, and fibrotic septa[3,4] using a short, focused RF energy pulse



Aneurysmal Septum Fibrotic Septum

Control your crossing through

- Reduced excessive tenting[3]
- Reduced mechanical force[4]
- Reduced needle jumping

TorFlex™ Transseptal Guiding Sheath

Radiopaque Band

Visualize distal sheath and dilator locations

Smooth Transition

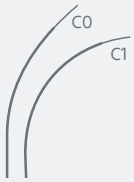
Facilitate advancement across septum with a sleek dilator-to-sheath profile

SMOOTH AND CONTROLLED CROSSING.™

NRG™ RF Transseptal Kit

CUSTOMIZE YOUR KIT

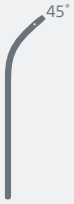
A Choose your needle curve



NRG™ Transseptal Needle

Needle length: 71 cm
Proximal gauge: 18 ga
Distal gauge: 21 ga

B Connect with the sheath



TorFlex™ Transseptal Guiding Sheath

French size compatibility: 8.5F (2.84 mm)
Sheath usable length: 63 cm
Dilator usable length: 67 cm

KIT MODEL NUMBERS

For use with Baylis Medical Company
Radiofrequency Puncture Generator RFP-100A*

	A		B	
NTK-71	0	-85	45	N
NTK-71	1	-85	45	N

NRG™ Transseptal Needle

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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TorFlex™ Transseptal Guiding Sheath

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

ADVERSE EVENTS: Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

EP-1515406-AA

*Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

[1]Rich ME, et al. J Vis Exp. doi: 10.3791/52811
[2]Rinaldi MJ, et al. Cardiac Interv Today. 2014 Mar-Apr.
[3]Sharma G, et al. Catheter Cardio Inte. doi: 10.1002/ccd.26608.
[4]Smelley MP, et al. J Cardiovasc Electr. doi: 10.1111/j.1540-8167.2009.01656.x

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